Adverse Reactions

Important Safety Information for FARXIGA (cont’d)

† Data based on a study of 46,720 Medicare patients with T2D who developed heart failure between 1994 and 1999.2

• Advise females of potential risk to a fetus especially during the second and third trimesters

Well-established safety profile

References:

1. Dosing

• FARXIGA is not recommended for patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

• For adults with T2D and multiple CV risk factors

FOR ADULTS WITH T2D AND MULTIPLE CV RISK FACTORS

"Covered without prior authorization" means that additional information is not required to be provided to the health plan in order for FARXIGA to be covered.

By Fingertip Formulary® as of February 22, 2019.

Pooled safety data for FARXIGA across clinical studies4

Warnings and Precautions

- Acute kidney injury 1.5% 2.0%
- Symptoms of volume depletion 2.5% 2.4%
- Genital infection* 0.9% 0.1%

DOSING

- As low as $0 for as long as you prescribe any available dose of FARXIGA.
- †

Selection of AEs of interest, % FARXIGA 10 mg

- Back pain 3.1% 4.2%
- Diastolic dysfunction 1.5% 1.7%
- Urolithiasis 1.0% 1.3%

CV=cardiovascular; CVOT=cardiovascular outcomes trial; DECLARE=Dapagliflozin Effect on Cardiovascular Events; SGLT2i=sodium-glucose cotransporter 2 inhibitors

FARXIGA is the only SGLT2i studied in a CVOT (Data from DECLARE-CV)

FARXIGA can cause intravascular volume depletion which may manifest as symptomatic hypotension.

Secondary prevention defined as established CV disease (clinically evident ischemic heart disease, ischemic cerebrovascular disease, or peripheral arterial disease). Nonfatal MI=9.7% 11.5% (Placebo vs FARXIGA)

Absolute risk reductions:

- MI=1.8% 2.8%
- CV events=2.1% 2.8%

P-Value for difference =<0.001

2020. Q1

Lactation:

Prepregnancy: If pregnant or breastfeeding, discontinue FARXIGA.

Pregnancy:

FARXIGA is not recommended for patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

Pregnancy Category C

Advise females of potential risk to a fetus especially during the second and third trimesters.

Breastfeeding:

FARXIGA can cause symptomatic hypotension in infants.

Intravascular volume depletion may occur in infants of mothers taking FARXIGA.

FARXIGA is not recommended for breastfeeding females.

For patients at high risk for ASCVD, or with established ASCVD or HFrEF

Regardless of glycemic control, an SGLT2i with proven efficacy (ie, dapagliflozin) is RECOMMENDED TO HELP PREVENT

HFrEF (NYHA class II-IV) with reduced ejection fraction

CV=cardiovascular; HFrEF=heart failure with reduced ejection fraction

The ADA 2020 guidelines recommend an SGLT2i for patients at high risk for ASCVD, or with established ASCVD or HFrEF

The treatment algorithm has changed

NEW AACE GUIDANCE FOR TYPE 2 DIABETES INCLUDES

Type 2 Diabetes Management Algorithm12

CARDIOVASCULAR OUTCOMES TRIAL PATIENTS WITH T2D†

HR=hazard ratio; MACE=major adverse cardiovascular events; MI=myocardial infarction; RRR=relative risk reduction.

CV=cardiovascular; CVOT=cardiovascular outcomes trial; DECLARE=Dapagliflozin Effect on Cardiovascular Events; SGLT2i=sodium-glucose cotransporter 2 inhibitors

* Data represented as event rates over a median follow-up of 4.2 years.

‡ As low as $0 for as long as you prescribe any available dose of FARXIGA.

FARXIGA is covered without prior authorization for the

ACCESS: Eligible commercially insured patients

Subject to eligibility. Restrictions apply.

Access to affordable nephrology is important to minimize the risk of hospitalization for heart failure in patients with type 2 diabetes mellitus and established cardiovascular disease.

Some cases were fatal. Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis.

FARXIGA, consider risk factors for ketoacidosis. Patients on FARXIGA may require monitoring and temporary discontinuation of treatment. If suspected, institute prompt treatment and discontinue FARXIGA.

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